REMARKS

Upon entry of the present amendment, claims 1, 3-4, and 6-24 are pending in the application. Claim 1 was amended to require a unidirectional inhalation valve and to lack an exhalation valve. The amendment is supported by disclosure at page 1, line 27, and page 8, line 9, of the specification. Claim 14 was amended to correct antecedent basis. New claims 23-24 were added; these claims are supported by disclosure at page 1, lines 25-26, of the specification.

No new matter has been added.

I. Rejections under 35 U.S.C. § 102

Claims 1-3, 6-18, and 21-22 were rejected for anticipation by Barney et al.

Claim 1 has been amended to require a unidirectional inhalation valve and to lack an exhalation valve. Barney et al. describe a collapsable drug delivery mask that contains no valves whatsoever. Since the claims now require a unidirectional inhalation valve, this reference does not anticipate the amended claims.

II. Rejections under 35 U.S.C. § 103

Claims 4 and 5 were rejected for anticipation by Barney et al. in view of Foley et al. (U.S. Patent No. 5,988,160). Applicant thanks the examiner for clarifying that the rejection is based on Barney et al. in view of Foley et al., rather than Crain in view of Foley et al. (as stated on page 4, line 22, of the Office Action). The Examiner stated:

> [Barney] teaches essentially all of the limitations except for wherein the device comprises a patient-actuated unidirectional inhalation valve. However, Foley does teach a patient-activated unidirectional inhalation valve so that air is retained for a second inhalation and medicament is not wasted. Therefore, it would be obvious to one of ordinary skill in the art to modify the device of [Barney] to include a patient-actuated unidirectional inhalation valve so that air is retained for a second inhalation and medicament is not wasted.

As is discussed above, Barney et al. describe a mask that is devoid of valves. Foley et al. describe a device that has two valves: an inhalation valve and an exhalation valve. The exhalation valve is unidirectional – "A one-way exhalation valve is provided in the mask, preferably at the far end of the nose accommodating extension for conveying exhaled air to the outside, and preventing entrance of outside air therethrough into said mask" – see abstract of Foley et al. There is no indication that the inhalation valve is unidirectional, merely that it opens and closes to permit or prevent air flow.

Claim 5 has been canceled. Claim 4, which depends from amended claim 1, requires a unidirectional inhalation valve and lacks an exhalation valve. This combination of references fails to describe or suggest a device with the structural elements now required by the amended claims. Therefore, withdrawal of this rejection is requested.

With respect to claims 19 and 20, the Examiner states:

> Barney fails to specifically teach the limitations with respect to particle size. However, such a limitation depends on the intended user along with the intended therapy and the type of medicament used (for particle size). Furthermore, Barney teaches (Col. 6, lines 25-27) that "one of skill will appreciate that practitioners may opt to aker dosages and/or formulations to fit a particular patient/animals needs." Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Barney to provide a particular particle size depending on the intended user along with the intended therapy and the type of medicament used.

This rejection is traversed. The Examiner's states that the particle size limitation "depends on the intended user along with the intended therapy and the type of medicament used". The method of claim 19 requires delivery of small drug particles (not exceeding 10 microns) to small airways of the lung using the device of claim 1, and claim 20 requires delivery of 3-5 micron particles to the same anatomical site. First, the claimed methods exclude particles generated by a vaporizer or nebulizer (which are greater than 20 microns; see page 2, lines 29-30, of the specification). Second, maintenance of a small particle size (1-5 microns such as that generated by a pressurized MDI container) depends on the exposure of dispensed drug particle to

exhaled (i.e., warm, moist) air. The specification teaches that rebreathing exhaled air leads to "condensation and clumping of particles. The resulting particles are too large to gain access to small airways" (page 3, lines 3-4, of the specification). The specification further teaches

> Exhalation into the same chamber into which drug is initially delivered causes the drug particles to condense, i.e., become larger, further decreasing the efficiency of drug delivery to the lung and small airways of the animal. Repeated inhalation/exhalation cycles further decrease the efficiency of drug delivery. (page 8, lines 22-25, of the specification).

Since the device required in the method of claims 19 and 20 requires a device with a unidirectional inhalation valve and lacking an exhalation valve, "[t]he horse can not exhale through the chamber, since there is no flow permitted in this direction." (page 10, line 5, of the specification). In contrast, airflow in the device of Barney is not restricted, and exhalation into the device occurs.

With Barney's device, any breath subsequent to an initial breath leads to an increase in medicament particle size. As is well known in the art, particles greater than 10 microns in size are trapped in the nose (see Morin et al., which was provided to the Examiner with the Response filed on August 28, 2002). Contrary to the Examiner's statement that it would be obvious "to modify the device of Barney to provide a particular particle size depending on the intended user along with the intended therapy and the type of medicament used", Barney provides no motivation whatsoever to maintain a small particle size.

The claims require delivery of an effective dose of the therapeutic composition in a single inhaled breath and delivery to small airways of the lung. Barney et al. does not describe or suggest a single inhaled breath delivery. As with previous devices, Barney et al. indicates that medicament is delivered "[a]s the animal breathes" (col. 1, line 37, of Barney). As is discussed above, the specification of the present application addresses the issue of repeated breathing (e.g., page 3, lines 3-4, and page 8, lines 22-25, of the specification). Furthermore, Barney does not

target or express any particular interest in targeting the small airways of the lung. In fact, Barney appears to focus on delivery to upper respiratory tissues, stating "The device 25 may be used for any drug formulation which may be advantageously administered to the lung or nasal passages in an animal....." (col. 6, lines 16-19, of Barney).

In view of Barney's failure to describe a device with the claimed structural elements (e.g., unidirectional inhalation valve) and Barney's failure to describe single inhalation delivery of micron size particles to a specific anatomic site, i.e., small airways, Applicant submits that the claims are nonobvious over the cited art.

CONCLUSION

Applicants submit that the application is in condition for allowance and such action is respectfully requested.

A petition for extension of time and a check in the amount of $475.00 is enclosed to cover the petition fee for a three month extension of time pursuant to 37 C.F.R. § 1.17(a)(3). The Commissioner is hereby authorized to charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 21629-001.

Should any questions or issues arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

/IABeattie/

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